K121196

AUG 31 2012

510(k) Summary
per 21 CFR §807.92

Submitter's Name and Address	Boston Scientific Corporation Cardiovascular, Rhythm & Vascular Division One Scimed Place Maple Grove, MN 55311 Phone: 763-494-1700 Fax: 763-494-2222		
Contact Name and Information	Vicky L. Hagens Principal Regulatory Affairs Specialist Phone: 763-255-0303 Fax: 763-494-2222 e-mail: vicky.hagens@bsci.com		
Date Prepared	16 April 2012		
Proprietary Name	Emerge™ Monorail (MR) and Over-The-Wire (OTW) PTCA Dilatation Catheter		
Common Name	Percutaneous Transluminal Coronary Angioplasty (PTCA) Dilatation Catheter		
Product Code	LOX		
Classification	Class II, 21 CFR Part 870.5100		
Predicate Devices	Emerge™ PTCA Dilatation Catheter	K113220	22 March 2012
	Apex™ PTCA Dilatation Catheter	P860019 /S208	07 November 2008
Device Description	The Boston Scientific Emerge™ PTCA Dilatation Catheter is a sterile, single-use, intravascular medical device. The catheter consists of a shaft with a balloon near the distal tip. The balloon is designed to provide an inflatable segment of known diameter and length at recommended pressures. The Emerge™ PTCA Dilatation Catheter is offered in both Monorail (MR) and Over-the-Wire (OTW) platforms. There are radiopaque marker bands located under the balloon to aid in positioning the system during the procedure. Coatings are applied to the balloon and catheter to enhance insertion and withdrawal performance. The Emerge™ PTCA Dilatation Catheter will be available with balloon diameters of 1.50 mm and balloon lengths 8 mm to 20 mm.		
Intended Use of Device	The Emerge™ PTCA Dilatation Catheter (1.50 mm diameter) is intended for dilatation of stenosis in coronary arteries or bypass grafts.		
Indications for Use	The Emerge™ Over-The-Wire and Emerge Monorail PTCA Dilatation Catheters are indicated for the balloon catheter dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion. Emerge Over-The-Wire and Emerge Monorail PTCA Dilatation Catheters (balloon models 2.00 – 4.00 mm) are also indicated for the post-delivery expansion of balloon expandable stents (bare metal and drug-eluting).		

Comparison of Technological Characteristics	The Emerge™ PTCA Dilatation Catheter (1.50 mm diameter) incorporates substantially equivalent device materials and design, packaging materials and design, fundamental technology, manufacturing processes, sterilization process and intended use as those featured in the Boston Scientific predicate devices, Emerge™ PTCA Dilatation Catheter K113220 (cleared March 22, 2012) and Apex™ PTCA Dilatation Catheter P860019/S208 (approved November 7, 2008)
Performance Data	The Emerge™ PTCA Dilatation Catheter was subjected to testing according to the requirements of *Guidance for Industry and FDA Staff – Class II Special Controls for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters*, September 8, 2010. Bench testing and biocompatibility testing were performed to support a determination of substantial equivalence. The results of these tests provide reasonable assurance that the proposed device has been designed and tested to assure conformance to the requirements for its intended use. No new safety or performance issues were raised during the testing and, therefore, these devices may be considered substantially equivalent to the predicate devices. The following biocompatibility and chemical characterization tests were completed on the Emerge™ PTCA Dilatation Catheter: Cytotoxicity — Hemolysis (Direct Contact) Sensitization — Hemolysis (Extract Method) Intracutaneous Reactivity — Complement Activation Acute Systemic Toxicity — Coagulation Materials Mediated Pyrogenicity — In Vitro Hemocompatibility USP Physicochemical — FTIR Analysis (Additional Characterization Tests – residual NPGDA analysis) The following in-vitro performance tests were completed on the Emerge™ PTCA Dilatation Catheter: Effective Length — Balloon Inflation/Deflation Time Shaft Inner and Outer Diameter — Catheter Bond Strength Tensile Balloon Crossing Profile — Tip Pull Test Balloon Preparation, Deployment, and Retraction — Flexibility and Kink Withdrawal into a Guide Catheter — Torque Strength Shaft and Bond Burst Pressure — Radiopacity Balloon Rated Burst Pressure — Coating Integrity Balloon Fatigue (Repeat Inflations) — Particulate Evaluation Balloon Compliance
Conclusion	Based on the indications for use, technological characteristics, and safety and performance testing, the Emerge™ PTCA Dilatation Catheter has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the Boston Scientific predicate devices, Emerge™ and Apex™ PTCA Dilatation Catheters.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Boston Scientific Corporation
c/o Ms. Vicky Hagens
Principal Regulatory Affairs Specialist
One Scimed Place
Maple Grove, MN 55311

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Re: K121196
Trade Name: Emerge™ PTCA Dilatation Catheter
Regulation Number: 21 CFR 870.5100
Regulation Name: Standard PTCA Catheter
Regulatory Class: Class II
Product Code: LOX
Dated: August 16, 2012
Received: August 17, 2012

Dear Ms. Hagens:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K121196

Device Name: Emerge™ Monorail (MR) and Over-The-Wire (OTW) PTCA Dilatation Catheter

Indications for Use:

The Emerge™ Over-The-Wire and Emerge Monorail PTCA Dilatation Catheters are indicated for the balloon catheter dilatation of the stenotic portion of a coronary artery or bypass graft stenosis for the purpose of improving myocardial perfusion. Emerge Over-The-Wire and Emerge Monorail PTCA Dilatation Catheters (balloon models 2.00 – 4.00 mm) are also indicated for the post-delivery expansion of balloon expandable stents (bare metal and drug-eluting).

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

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